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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,584	03/09/2004	David G. Benditt	021628-001010US	4713

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,584	BENDITT ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *4,6-14,16,17,22,25-27,31 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,15,18,19 and 32-35* is/are rejected.

7)☒ Claim(s) *20,21,23,24 and 28-30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 4, 6-14, 16, 17, 22, 25-27, 31, and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/27/06.

The applicants did not explicitly state that the elected species I between species J and I. However, the applicants did withdraw claim 31, which is drawn to species J and left pending claim 30, which is drawn to species I. It appears from these actions that the applicants intended to elect species I.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: reference numeral 18. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by

the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the sensor, wherein the catheter of the sensor extends through a wall and inside a lumen of the blood vessel and the transducer of the sensor resides outside of the blood vessel, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

This application has been filed with informal drawings acceptable for examination purposes only. Upon allowance of the application, formal drawings will be required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> Or
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 5, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,575,914 to Rock et al. Rock teaches a method for detecting and treating inadequate tissue perfusion of a patient, wherein a sensor 100, 120, 410, 420 is provided for measuring an intravascular blood parameter and the sensor is positioned on a portion of the patient's vasculature. The intravascular parameter is measured using the sensor and inadequate tissue perfusion is detected based on the intravascular parameter measured by the sensor. A stimulus is delivered to increase tissue perfusion

as a function of the measured intravascular parameter (figs. 6 and 7; col. 4, lines 8-26; col. 5, lines 1-17; col. 5, line 45- col. 6, line 18; col. 7, lines 5-52 of Rock).

Regarding claim 5, the sensor is positioned on an artery (col. 4, line 67-col. 5, line 1; col. 5, lines 50-52 of Rock).

Regarding claim 15, a therapeutic device 210, 220for delivering the stimulus to increase tissue perfusion is provided at a location on the patient remote from the sensor 100 (figs. 3 & 6 of Rock).

Claims 1, 2, 5, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,616,624 to Kieval. Kieval teaches a method for detecting and treating inadequate tissue perfusion wherein a sensor 30 is provided for measuring an intravascular blood parameter, the sensor is positioned on a portion of the patient's vasculature, and the intravascular parameter is measured using the sensor 30 (fig. 2; col. 6, lines 1-29 of Kieval). Inadequate tissue perfusion is detected based on the intravascular parameter measured by the sensor and a stimulus is delivered to increase tissue perfusion as a function of the measured intravascular parameter (col. 6, lines 1-40, col. 7, lines 15-47; col. 10, lines 12-22 of Kieval).

Regarding claim 2 and 5, the sensor 30 measured blood pressure and the sensor 30 is positioned on a blood vessel or artery (fig. 2; col. 6, lines 5-27; col. 6, lines 46-50 of Kieval)

Regarding claim 15, the stimulus is delivered by a therapeutic device 50, 60, 70, 80 positioned at a location remote form the sensor 30 (fig. 1; col. 6, lines 1-40 of Kieval).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval, as applied to claims 1, 2, 5, and 15 above, and further in view of US Patent No. 6,033,366 to Brockway et al. Kieval lacks using a sensor including a transducer and catheter wherein the catheter extends through a wall and inside a lumen of the blood vessel and the transducer resides outside of the blood vessel. However, Brockway teaches a pressure sensor comprising a catheter 22 and a transducer 30 wherein, during use of the sensor, the catheter 22 is inserted through the wall into a blood vessel and the transducer 30 resides outside of the vessel (fig. 6; col. 5, lines 5-32; col. 11, line 66-col. 12, line 18 of Brockway). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the sensor of Brockway in place of the sensor of Kieval, as it is merely the substitution of one known means of sensing blood pressure for another.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rock, as applied to claims 1, 5, and 15 above, and further in view of International Publication Number WO 98/51212 to Dunlop. In the method of Rock, blood flow, but

not heart rate, is detected as an indicator of inadequate tissue perfusion. However, Dunlop teaches a method of monitoring a patient's perfusion index, wherein both blood flow and heart rate are detected as indicators of inadequate tissue perfusion and the two values are used in combination to determine inadequate tissue perfusion (pp.20-23 of Dunlop). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use both heart rate and blood flow as indicators of perfusion in the method of Rock, since Dunlop teaches that adjusting the blood flow with heart rate as a co-variant factor produces a more accurate assessment of perfusion than using just blood flow (p. 22, line 13- p. 33, line 27 of Dunlop).

Regarding claim 19, a therapeutic device is provided to deliver the stimulus (fig. 1; col. 4, lines 25-26; col. 5, lines 13-17 of Rock).

Claims 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,899,751 to Cohen in view of US Patent No. 6,033,366 to Brockway et al. Cohen teaches a medical method wherein an implantable therapeutic device 12, 21, 22 configured to deliver a stimulus to increase heart rate is provided and implanted in a patient (fig. 1; col. 8, lines 15-.44 of Cohen). An implantable pressure sensing device 20 is provided and implanted in the patient such that at least a portion of the pressure sensing device resides in a vascular lumen (figs. 1, 2C, 2F; col. 9, lines 45-56; col. 10, line 65-col. 10, line 5 of Cohen). The pressure-sensing device 20 is connected to the implantable therapeutic device 12, 21, 22 via an electrical lead 19, 19a (fig. 1 of Cohen). The implantable therapeutic device 12, 21, 22 is operated to deliver the stimulus to

increase heart rate in response to a drop in blood pressure as measured by the pressure sensing device 12, 13, 19a, 20 (fig. 4; col. 10, lines 25-69; col.11, line 7-col. 12, line 63 of Cohen). Cohen lacks the pressure-sensing device comprising a hermetically sealed housing and pressure transmission catheter.

However, Brockway teaches an implantable pressure sensing device (PSD) 20 including a hermetically sealed housing 32, a pressure transducer 30 disposed in the housing 32, and a pressure transmission catheter (PTC) 22 having a proximal end, a distal end, and a lumen extending therethrough, with the proximal end of the PTC 222 connected to the housing 32 and the lumen of the PTC in fluid communication with the pressure transducer 30 (fig. 1; col. 5, lines 6-20; col. 7, lines 20-24 of Brockway). When inserted into a blood vessel to measure blood pressure, the PSD 20 is implanted such that the distal end of the PTC resides in the vascular lumen and the housing remains outside the vascular lumen (Fig. 7; col. 1, line 65-col. 12, line 18 of Brockway). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the pressure sensing device of Brockway in place of the pressure transducer of Cohen, as it is merely the substitution of one known means of measuring blood pressure for another.

Regarding claim 33, the pressure transducer 30 of the PSD 20 converts a pressure signal to an electrical signal (Col. 5, lines 18-25 of Brockway) and the ITD 12, 21, 22 includes a signal processor that evaluates the electrical pressure signal for hypotension (figs. 3 & 4; col. 8, lines 37-45; col. 10, line 13-col. 12, line 63; col. 13, lines 20-33 of Cohen), wherein Cohen teaches effecting stimulation or change in stimulation

when the blood pressure departs from the mean baseline by a predetermined amount and that amount may include an amount below the baseline or hypotension.

Regarding claim 34, the lumen of the PTC 22 is filled with a fluid 52, 60 and a barrier 52 is disposed in a distal end of the PTC 22 lumen to contain the fluid while permitting pressure to be transferred therethrough (figs. 1, 2A-D; col. 5, line 66-col. 7, line 18 of Brockway).

Regarding claim 35, the ITD delivers an electrical stimulus (fig. 3; col. 8, lines 37-44 of Cohen).

Allowable Subject Matter

Claims 20, 21, 23, 24, and 28-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

With regard to claims 20, 21, 23, 24, and 28-30, the prior art of record fails to teach or fairly suggest a medical method for treating a patient wherein a therapeutic device is provided for delivering a stimulus to increase tissue perfusion, wherein the stimulus increases heart rate, in combination with all of the other limitations of the claims. Rock, in view of Dunlop suggests all of the limitations of claim 20 except that the delivered stimulus is a defibrillating stimulus, rather than one to increase heart rate. In fact, the prior art indicates that an increase in heart rate results in a decrease in perfusion, rather than an increase of perfusion (see col. 2, lines 12-13 of US Patent No.

6,510,342 to Park et al.; see also paragraph 5 of US Patent Application Publication No. 2003/0229380 to Adams et al.)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari
Patent Examiner
Art Unit 3736

ROBERT L. NASSER
PRIMARY EXAMINER